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Notice of Non-responsive Amendment 02/02/2006
Reply 03/02/2006

REMARKS

Enclosed herein is a Supplemental Reply in response to the Notice of a Non-Responsive Amendment. While not conceding the correctness of the Examiner's position, in the interest of advancing prosecution, Applicants have expanded the responses to the 35 USC §112 rejections.

Rejections under 35 USC §112 ¶2

All previously pending Claims are canceled and as such, the instant rejections are moot. Nonetheless, the new Claims contained herein are derived from said canceled Claims and thusly, the allegedly indefinite areas of concern for the Examiner will be addressed.

Claims 46 and 48 are rejected under 35 USC §112 ¶2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully disagree.

Determining whether a claim is definite requires an analysis of whether one skilled in the art would understand the bounds of the claim when read in light of the specification. If the Claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, §112 demands no more. (*See Miles Lab., Inc. v. Shandon, Inc.*, 997 F.2d 870, 875, (Fed. Cir. 1993).

It is well settled that the "language of the claims, read in light of the specification" is to be considered when determining whether the Claims are definite. (*Allen Archery Inc. v Browning MFG. Co.*, 819 F.2d 1087, 1092 (Fed. Cir. 1987)). This precept has been incorporated into the MPEP which states that "[t]he meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its import." (MPEP §608.01(o)). *See also* 37 CFR 1.75 (c) wherein it states in part that "the meaning of the terms in the claims may be ascertainable by reference to the description."

Moreover, the definiteness of the language employed "must be analyzed - not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing ordinary skill in the pertinent art." (*In re Angstadt*, 537 F.2d 498, 501 (C.C.P.A. 1976)(quoting *In re Moore*, 439 F.2d 1232,1235 (C.C.P.A. 1971)). The law is clear that "if the claims, read in the light of the specifications, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and

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if the language is as precise as the subject matter permits, the courts can demand no more." (*North Am. Vaccine, Inc. v American Cyanamid Co.*, 7 F.3d 1571, 1579-1580 (Fed. Cir. 1993)).

The Examiner believes the term "homolog" is not disclosed in the Specification. The term "homolog" is well understood by one of ordinary skill in the art. Additionally, the Examiner is directed to the paragraph beginning on page 5, line 30, of the instant Specification wherein a description of the term "homolog" is provided. The Examiner also believes the term "isoenzyme" is not disclosed in the Specification. The term "isoenzyme" is well understood by one of ordinary skill in the art. The Examiner is directed to page 6, line 18, of the Specification wherein a description of the term "isoenzyme" is provided.

The Examiner believes there is a lack of support for the genus of nucleotides related to SEQ ID NO:1. Applicants respectfully disagree. Applicants assert that the nucleotide sequences disclosed on pages 20 and 28-29 of the instant Specification constitute disclosure of a representative number of species to describe the genus.

The Examiner asserts that the term "about" in the phrase "at least about" is a relative term and as such, renders the instant Claims indefinite. Contrary to said assertion, the MPEP section does not require terms to be exactly clear but merely clear enough for one of ordinary skill in the art to well understand (See MPEP 2173.05(b)). Said MPEP section, additionally states, in part:

claims reciting "at least about" were invalid for indefiniteness where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term "about." *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).

The aforementioned MPEP section providing the reason rejecting "at least about" for indefiniteness is distinguished from the instant invention because in the instant Specification, a range of specific activity is taught. The Examiner is directed to page 6, lines 9-13, wherein the instant Specification of the instant invention provides indication of the range of specific activity that is covered by the term "about."

All other §112 ¶2 rejections have been addressed in the new Claims contained herein.

Accordingly, Applicants assert that the instant Claims, when read in light of the instant Specification, are definite and respectfully request withdrawal of the instant rejection under 35 USC § 112. Favorable action is solicited.

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Rejections under 35 USC §112 ¶1

Claims 30-32 are rejected under 35 USC §112 ¶1 as containing subject matter which was not described in the specification in such a way as to enable one skilled in the relevant art that the inventors, at the time the Application was filed, had possession of the claimed invention. Applicants respectfully disagree.

In regards to all the 112 ¶1 rejections, it must be remembered that to satisfy the written description prong of 35 USC §112 ¶1, the Specification must only describe the invention in sufficient detail so that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). No particular form of disclosure is required, but "the description must clearly allow persons of ordinary skill in the art to recognize that [the patentee] invented what is claimed." *In re Gösteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989) (citing *In re Wertheim*, 541 F.2d 257, 262 (C.C.P.A. 1976)).

The MPEP states that a "[d]escription of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces" and as such, a single species may be enough to identify the entire genus (see MPEP 2163.II.A.3.a.ii.). A recent Federal Circuit case supports the statements of the MPEP. When discussing what is required for a written description the court said "[t]he 'written description' requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution" (*Capon v. Eshhar*, 418 F.3d 1349, 1358; 2005).

Applicants assert that the instant Specification fully complies with these requirements because it allows one of ordinary skill in the art to practice the invention. The claims are rewritten in such a manner that the problems described by the Examiner in the Office Action no longer apply. For instance, the term "functional" as related to the Claims is more clearly defined, e.g. Claim 50 a) ii). Further, Applicants have supplied five sequences of PDAT genes which provide exemplifications of the instant invention when not even a single example is required to fulfill the written description requirement. As noted above, all that is required is a

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description of the invention. Accordingly, the instant Application does provide an adequate written description for one of ordinary skill in the art to practice the instant invention.

Regarding the enablement requirement of §112, the Federal Circuit has held that “[t]he specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if, given what they already know, the specification teaches those in the art enough that they can make and use the invention without ‘undue experimentation’.” (*Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1334 (Fed. Cir. (2003))). The Claims as currently amended are fully enabled by the Specification of the instant application in combination with the general knowledge of one of ordinary skill in the art.

Further as described in *Capon*, as the skill in the art progresses so does the analysis of the inventions in said art. The Examiner alleges that the instant disclosure presents no guidance or working examples of the use of the genus of transgenic cells and transgenic organisms or genus of nucleotides included in the scope of the claims. Applying *Capon* and the relative state of the art at the time of filing, one of ordinary skill would be able to create the working examples the Examiner asserts are lacking. The skill in the art at the time of filing was such that creation of transgenic organisms, in general, was routine.

Further still, the Examiner need only look to the USPTO itself for references for the screening that allegedly cannot occur. The numerous Affymetrix patents clearly show that large scale screening was and is state of the art and that a comparison of a sufficient number of sequences of PDATs to the disclosed PDATs can be performed; no undue experimentation would be required. Moreover, computational techniques were available at the time of filing for structural predictions based on sequence listings. (See e.g., The Boston University Protein Sequence Analysis server available at <http://bmerc-www.bu.edu/psa/>).

Applicants respectfully submit that for at least the reasons listed above the rejections under 35 USC §112, first and second paragraphs should be withdrawn and an indication of allowance should appear in the next paper from the Office. Favorable action is solicited.